DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Ms. Elizabeth Paul
Manager, Regulatory Affairs
ConMed Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K050519
Trade/Device Name: Advantage Turbo® Drive System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: II
Product Code: GEY
Dated: March 15, 2005
Received: May 2, 2005

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050519

Indications for Use

510(k) Number (if known): K050519

Device Name: Advantage Turbo® Drive System

Indications for Use:

The Advantage® Turbo Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...eurological Devices
K050519

K050519

PROPRIETARY INFORMATION – LINVATEC CORPORATION

February 18, 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the Special 510(k) Summary of Safety and Effectiveness for the Advantage® Turbo Drive System.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Revised

Elizabeth Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: Advantage® Turbo Drive System

Common Name: Drive System

Classification Names:
1. Ear, Nose and Throat Electrical or Pneumatic Surgical Drill 874.4250
2. Electric Cranial Drill Motor 882.4250
3. Bone Cutting Instrument and Accessories 872.4120
4. Surgical Instrument Motors and Accessories

Proposed Class/Device: Class II

Product Codes: HRX, ~~ERL~~

Advantage® Turbo Drive System
Special 510(k) # K050519
February 18, 2005

D. Predicate/Legally Marketed Devices

Advantage Drive System K002523
Linvatec Corporation

E. Device Description

The Advantage® Turbo Drive System device description is identical to the original submission except for the modifications listed below.

The modifications described in this Special 510(K) are listed below:

1. A new motor has been installed which provides additional torque and speed to the handpiece.

2. The software, Version 7.0, has been modified to allow Advantage® Turbo Drive System to run at a maximum forward/reverse speed of 10,000 RMP or 12,000 RPM. This maximum speed is selectable using an appropriate code during the calibration request. All other software parameters used to run the Advantage® Turbo Drive System operate in the same manner as all pre-existing software versions.

These modifications do not affect the device's intended use, fundamental scientific technology or performance specifications so that any new issues regarding safety and effectiveness are raised.

Intended Use

The Advantage® Turbo Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

F. Substantial Equivalence

The Advantage® Turbo Drive System is substantially equivalent in intended use, scientific technology and design to the Advantage Drive System. The Advantage Drive System was cleared by FDA under 510(k) K002523. The changes made to the Advantage Drive System have been tested to assure that the proposed modifications do not raise any new issues regarding safety and effectiveness.